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EXAMINER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte SEBASTIEN HOLVOET, ANNICK MERCENIER,
MARIETTA WEISS, and ADRIAN WALTER ZUERCHER¹

Appeal 2016-005907
Application 14/372,978
Technology Center 1600

Before DEMETRA J. MILLS, RICHARD J. SMITH, and DAVID COTTA,
Administrative Patent Judges.

SMITH, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method for reducing the symptoms of allergies that have been rejected as obvious.

We have jurisdiction under 35 U.S.C. § 6(b).

We affirm-in-part.

¹ According to Appellants, the real party in interest is Nestec S.A. (Appeal Br. 2.)

STATEMENT OF THE CASE

Claims on Appeal

Claims 1–13 are on appeal. (Claims Appendix, Appeal Br. 14–15.)

Claim 1, the only independent claim, is illustrative and reads as follows:

1. A method for reducing the symptoms of allergies in patients having allergies triggered by food, respiratory or contact allergens, the method comprising administering a composition comprising at least one *Lactobacillus helveticus* strain selected from the group consisting of *Lactobacillus helveticus* NCC 1176, *Lactobacillus helveticus* NCC 714 and combinations thereof to an individual in need of same.

Examiner's Rejections

1. Claims 1–5 and 7–13 stand rejected under pre-AIA 35 U.S.C. § 103(a) as unpatentable over Nielsen.² (Ans. 2–4.)
2. Claims 1–13 stand rejected under pre-AIA 35 U.S.C. § 103(a) as unpatentable over Flambard.³ (*Id.* at 4–6.)

FINDINGS OF FACT

Except as otherwise indicated, we adopt as our own the Examiner's findings regarding the scope and content of the prior art. The following findings are included for emphasis and reference purposes.

FF 1. The Specification states that “*Lactobacillus helveticus* (L helveticus) strain NCC 1176 (Nestlé Culture Collection reference 1176), is also named LH91 and was deposited with the INSTITUT PASTEUR, 25 rue

² Nielsen et al., WO 2005/060937 A1, pub. July 7, 2005 (“Nielsen”).

³ Flambard, US 2010/0273239 A1, pub. Oct. 28, 2010 (“Flambard”).

du Docteur Roux, F-75724 PARIS Cedex 15 on October 1991 as CNCM I-1156.” (Spec. 9, ll. 9–12.)⁴

FF 2. The Specification states that “*Lactobacillus helveticus* (L helveticus) strain NCC 714 (Nestlé Culture Collection reference 714), was deposited with the INSTITUT PASTEUR, 25 rue du Docteur Roux, F-75724 PARIS Cedex 15 on October 1991 as CNCM I-1154.”⁵ (*Id.* at ll. 19–21.)

FF 3. The Examiner finds that Nielsen teaches a composition for the treatment of allergies that uses *Lactobacillus helveticus*. (Ans. 2, citing Nielsen 5, l. 34 and 12, ll. 23–24.)

FF 4. The Examiner finds that Flambard teaches a composition comprising *Lactobacillus helveticus* for the treatment of an allergy. (Ans. 4, citing Flambard Abstract.)

DISCUSSION

Except as otherwise indicated, we adopt as our own the Examiner’s findings, analysis, and conclusions as set forth in the Final Action (Final Act. 3–8, dated June 4, 2015) and Answer (Ans. 2–9).

⁴ The Specification indicates that the same microorganism may be identified by different nomenclature. (Spec. 9, ll. 9–10.)

⁵ The Institut Pasteur is a recognized microorganism depository under the Budapest Treaty for the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure. 37 C.F.R. §1.801-1.809. 37 C.F.R §1.802 states that, “Once deposited in a depository complying with these regulations, a biological material will be considered to be readily available even though some requirement of law or regulation of the United States or of the country in which the depository institution is located permits access to the material only under conditions imposed for safety, public health or similar reasons.”

Issue

Whether a preponderance of evidence of record supports the Examiner's rejections under 35 U.S.C. § 103(a).

Analysis

Rejection No. 1

Claim 1

The Examiner finds that Nielsen teaches *Lactobacillus helveticus* to treat allergies. (FF 3.) The Examiner concludes:

It would have been obvious to one of ordinary skill to substitute and use the recited strains of *L. helveticus* in the method of Nielsen. Nielsen [] disclose[s] a method of treating allergies comprising administering *L. helveticus*, and teaches that this species of *Lactobacillus* has probiotic properties. Thus, one of ordinary skill would have a reasonable expectation of success using any strain of *Lactobacillus helveticus*.

(Ans. 2–3.)

Appellants argue that Nielsen does not disclose the claimed strains (NCC 1176 or NCC 714) that the Specification shows exhibit “increased efficacy” over a different strain of *L. Helveticus* (NCC 2849), that the art shows that health benefits conferred by a specific bacterial strain are strain specific, and that the Examiner has not shown that the claimed strains were publicly known before the time of the invention. (Appeal Br. 6–8; *see also* Reply Br. 2–3.)

We find that the Examiner has the better position. We address Appellants' arguments below.

Claimed Strains, Specification Experiments, and Strain Specificity

Appellants argue that Nielsen does not disclose the claimed strains (NCC 1176 or NCC 714). (Appeal Br. 6.) However, the rejection before us is an obviousness rejection, not an anticipation rejection. The determination to be made is what would have been obvious to one of ordinary skill in the art at the time of the invention. In the present case, Nielsen discloses that at the time of the invention that *L. helveticus* was known to treat allergies. (FF 3.) As held by *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007):

The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007).

If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.

Id. at 417. In the present case, Appellants have merely implemented a predictable variation of a known method (Nielsen), that *L. helveticus* strains treat allergies.

Appellants argue that data in the Specification “shows that consumption of *L. helveticus* NCC 1176 and/or 714 leads to reduced symptoms (primary, secondary prevention) in a mouse food allergy model,” and that this is “in contrast to *L. helveticus* NCC 2849.” (Appeal Br. 7, citing Spec. 9, l. 23–10, l. 4 and 20, l. 22–21, l. 3.) However, it appears from the data in the Specification that NCC 2849 exhibited some anti-allergy

properties. (Spec. 18, ll. 18–27.) Appellants have provided no evidence that other strains of *L. helveticus* showed no efficacy in treating allergies.

Moreover, while Appellants argue that the “specification demonstrates the increased efficacy of the claimed strains over a different strain of *L. helveticus*, namely *L. helveticus* NCC 2849,” (Appeal. Br. 6), Appellants have not established with appropriate evidence that the treatment of allergies with the claimed *L. helveticus* strains was unexpected in view of the disclosure of Nielsen that *L. helveticus* was known to treat allergies. For example, Appellants provide no comparative evidence with the *Lactobacillus helveticus* strain DSM14998, or *Lactobacillus helveticus* strain DSM14997, disclosed in Nielsen. (Nielsen 6.)

In order for a showing of “unexpected results” to be probative evidence of non-obviousness, it falls upon the applicant to at least establish: (1) that there actually is a difference between the results obtained through the claimed invention and those of the prior art . . . ; and (2) that the difference actually obtained would not have been expected by one skilled in the art at the time of invention.

In re Freeman, 474 F.2d 1318, 1324 (CCPA 1973) (citations omitted).

Appellants’ contend that the Specification experiments “are an example of the **strain specificity** of the health benefits of probiotics.” (Appeal Br. 7.) Appellants also point to publications by Senok⁶ and Sanders⁷ to buttress their argument that the health benefits of probiotics are strain specific. (*Id.*) However, Appellants merely rely on general statements in Senok and Sanders regarding strain specificity. Furthermore, Appellants

⁶ Senok et al., *Probiotics: facts and myths*, Clin. Microbiol. Infect. 11, 958–66 (2005).

⁷ Sanders, *Probiotics: strains matter*, NewHope360°, 1–8 (2007).

appear to be arguing that a person of skill in the art would not have had a reasonable expectation of success in arriving at the claimed invention because different strains have different properties, but we are not persuaded. We agree with the Examiner that a reasonable expectation of success exists from choosing a strain within the genus/species (*L. helveticus*) that has the function of treating allergies, as taught by Nielsen. (Ans. 7.) *See In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988) (“Obviousness does not require absolute predictability of success. Indeed, for many inventions that seem quite obvious, there is no absolute predictability of success until the invention is reduced to practice.”). Here, given Nielsen’s teaching that *L. helveticus* can be used to treat allergies, one of ordinary skill in the art would have had a reasonable expectation of success in determining which strains of that genus/species provide that treatment.

Knowledge of Strains

Appellants argue that “the Examiner has not shown that *L. helveticus* NCC 1176 or *L. helveticus* NCC 714 were even publicly known before the time of the claimed invention.” (Appeal Br. 8.) We are not persuaded. Appellants do not assert that they discovered the claimed strains or that they are new. In fact, the deposit of the claimed strains in 1991, at the Institute Pasteur, a Budapest Treaty Depository, as acknowledged in the Specification, establishes that these strains were publicly known for over twenty years prior to Appellants’ filing date.⁸ (FF 1, 2.)

⁸ *See* 37 C.F.R. § 1.802 regarding public availability of deposits.

Claim 7

Claim 7 depends on claim 1 and further recites “wherein the composition comprises cereal proteins and/or hydrolyzed proteins.” (Appeal Br. 14.) The Examiner asserts that Nielsen “teaches caseinate (hence, a hydrolyzed protein).” (Ans. 3, 7.) Appellants argue that “caseinate is not a hydrolyzed protein; caseinate is merely a soluble salt of the milk protein casein.” (Reply Br. 4.)

We find that Appellants have the better position. The Examiner does not explain how or why caseinate is a hydrolyzed protein; rather, the Examiner makes a conclusory statement without a basis in the record for the statement. However, “rejections on obviousness grounds cannot be sustained by mere conclusory statements.” *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006).

Conclusions of Law

A preponderance of evidence of record supports the Examiner’s rejection of claim 1 under 35 U.S.C. § 103(a) over Nielsen. Claims 2–5 and 8–13 were not argued separately and fall with claim 1.

A preponderance of evidence of record fails to support the Examiner’s rejection of claim 7 under 35 U.S.C. § 103(a) over Nielsen.

Rejection No. 2

Claim 1

The Examiner’s rejection based on Flambard sets forth essentially the same findings and analysis as with Nielsen, and Appellants advance essentially the same arguments in response, as set forth above. (*See* Ans. 4–

5 and 8–9; Appeal Br. 9–12 and Reply Br. 4–6.) Accordingly, for the reasons set forth above, we affirm the rejection of claim 1 over Flambard.

Claim 6

Claim 6 depends on claim 1 and further recites “wherein the composition comprises an apple extract comprising polyphenols.” (Appeal Br. 14.) The Examiner finds that “Flambard [] teach[es] the use of polyphenols to treat allergies (See [0009]). It would be obvious to use polyphenols from any source to enhance the effects of Flambard’s composition.” (Ans. 5.) Appellants argue that Flambard “actually teaches a **tea polyphenol**” (Appeal Br. 12) and that “the Examiner has not provided any evidence demonstrating apple extract has one or more polyphenols the same or similar to those in tea” (Reply Br. 6).

The Examiner bears the initial burden of establishing a prima facie case of obviousness and has not done so. *See In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). Here, we agree with Appellants that the Examiner has not established that an apple extract has one or more polyphenols the same or similar to those in tea. The rejection of claim 6 is reversed.

Conclusions of Law

A preponderance of evidence of record supports the Examiner’s rejection of claim 1 under 35 U.S.C. § 103(a) over Flambard. Claims 2–5 and 7–13 were not argued separately and fall with claim 1.

A preponderance of evidence of record fails to support the Examiner’s rejection of claim 6 under 35 U.S.C. § 103(a) over Flambard.

SUMMARY

We affirm the rejection of claims 1–5 and 8–13 under 35 U.S.C. § 103(a) over Nielsen.

We reverse the rejection of claim 7 under 35 U.S.C. § 103(a) over Nielsen.

We affirm the rejection of claims 1–5 and 7–13 under 35 U.S.C. § 103(a) over Flambard.

We reverse the rejection of claim 6 under 35 U.S.C. § 103(a) over Flambard.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED-IN-PART